IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Focke et al.	
	Art Unit: To Be Assigned
Appl. No: To Be Assigned	Examiner: To Be Assigned
Filed: Herewith	Atty. Docket: 0273-0005
For: **Allergy Vaccines and Their Preparation**	

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination of the above-identified application, Applicants herewith respectfully request the following amendments:

In the Claims:

Please cancel claims 10-13 and 25-27 without prejudice to or disclaimer of the subject matter therein.

Please amend the following claims:

1. (once amended) A pharmaceutical composition, containing a peptide and a pharmaceutically acceptable carrier or diluent, wherein the peptide:

a) has a length of 8 to 50 amino acids; and

b) has at least three preferably consecutive amino acids identical to at least three solvent-exposed amino acids of an allergenic protein which appear in close vicinity on the molecular surface of the allergenic protein.

2. (once amended) A pharmaceutical composition according to claim 1, wherein said at least three solvent-exposed amino acids appear on the molecular surface of the allergenic protein within a surface patch of approximately 500 square Angström.

3. (once amended) A pharmaceutical composition according to claim 1, wherein at least five consecutive amino acids of the peptide are identical to at least five consecutive solvent-exposed amino acids of the allergenic protein.

4. (once amended) A pharmaceutical composition according to claim 1, further containing an adjuvant.

5. (once amended) A pharmaceutical composition according to claim 1, wherein all amino acids of the peptide except one are identical to the amino acids of an amino acid sequence which is part of the allergenic protein amino acid sequence.

6. (once amended) A pharmaceutical composition according to claim 5, wherein the one amino acid which deviates from the amino acid sequence of the allergenic protein is the N-terminal or C-terminal amino acid of the peptide amino acid sequence.

7. (once amended) A pharmaceutical composition according to claim 1, wherein the amino acid sequence of the peptide is identical to an amino acid sequence which is part of the allergenic protein amino acid sequence.

8. (once amended) A pharmaceutical composition according to claim 1, wherein the allergenic protein is the birch pollen allergen Bet v 1.

9. (once amended) A pharmaceutical composition according to claim 1, wherein the peptide amino acid sequence comprises at least the N-terminal or C-terminal five amino acids of the allergenic protein amino acid sequence.

14. (once amended) A method for preparing a pharmaceutical composition comprising:

a) determining which amino acids of a given allergenic protein are solvent-exposed on the surface of the allergenic protein;

b) preparing a peptide having a length of 8 to 50 amino acids, wherein at least three preferably consecutive amino acids of the peptide are identical to at least three solvent-exposed amino acids of the allergenic protein which appear in close vicinity on the molecular surface of the allergenic protein; and

c) optionally admixing the peptide with a pharmaceutically acceptable carrier or diluent.

15. (once amended) A method according to claim 14, wherein said at least three solvent-exposed amino acids appear on the molecular surface of the allergenic protein within a surface patch of approximately 500 square Angström.

16. (once amended) A method according to claim 14, wherein at least five consecutive amino acids of the peptide are identical to at least five consecutive solvent-exposed amino acids of the allergenic protein.

17. (once amended) A method according to claim 14, further comprising adding an adjuvant.

18. (once amended) A method according to claim 14, wherein all amino acids of the peptide except one are identical to the amino acids of an amino acid sequence which is part of the allergenic protein amino acid sequence.

19. (once amended) A method according to claim 18, wherein the one amino acid which deviates from the amino acid sequence of the allergenic protein is the N-terminal or C-terminal amino acid of the peptide amino acid sequence.

20. (once amended) A method according to claim 14, wherein the amino acid sequence of the peptide is identical to an amino acid sequence which is part of the allergenic protein amino acid sequence.

21. (once amended) A method according to claim 14, wherein the allergenic protein is the birch pollen allergen Bet v 1.

22. (once amended) A method according to claim 14, wherein the peptide amino acid sequence comprises at least the N-terminal or C-terminal five amino acids of the allergenic protein amino acid sequence.

23. (once amended) A method according to claim 14, wherein the solvent-exposed amino acids of the allergenic protein are determined by determining the hydrophilicity profile of the allergenic protein.

24. (once amended) A method according to claim 14, wherein the solvent-exposed amino acids of the allergenic protein are determined from the three-dimensional structure of the allergenic protein.

Please add the following new claims:

28. (new) A method for treating an allergic disease, comprising: administering to a patient in need thereof the pharmaceutical composition of claim 1.

29. (new) A method according to claim 28, wherein the at least three solvent-exposed amino acids appear on the molecular surface of the allergenic protein within a surface patch of approximately 500 square Angström.

30. (new) A method according to claim 28, wherein at least five consecutive amino acids of the peptide are identical to at least five consecutive solvent-exposed amino acids of the allergenic protein.

31. (new) A method according to claim 28, wherein the peptide, upon administration, is capable of inducing IgG antibodies which react with the allergenic protein.

32. (new) A method according to claim 31, wherein the induced IgG antibodies can reduce or prevent binding of IgE antibodies to the allergenic protein.

33. (new) A method according to claim 28, wherein the peptide, upon administration, does not induce a significant IgE response.

REMARKS

Claims 1-9, 14-24 and 28-33 are pending in the current application. Claims 1-9 and 14-24 have been amended to conform to domestic practice. Claims 10-13 and 25-27 have been canceled and claims 28-33 have been added to conform canceled claims 10-12 and 25-27 to domestic practice. Support for the amendments to claims 1-9 and 14-24 and for new claims 28-33 is found in, *inter alia*, original claims 1-27. This amendment is believed to introduce no new matter, and thus, its entry is respectfully requested.

Applicants believe that the present application is in condition for examination. If for any reason, the Examiner believes that personal communication will expedite prosecution of this application, then the Examiner is invited to contact the undersigned at the phone number provided.

Respectfully submitted,

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Marked-Up Version of the Amended Claims

1. (once amended) A pharmaceutical composition, containing a peptide and a pharmaceutically acceptable carrier or diluent, wherein the peptide:

a) [the peptide] has a length of 8 to 50 amino acids; and

b) has at least three preferably consecutive amino acids [of the peptide are] identical to at least three solvent-exposed amino acids of an allergenic protein which appear in close vicinity on the molecular surface of [an] the allergenic protein[;

c) said at least three amino acids are solvent-exposed amino acids in the allergenic protein].

2. (once amended) A pharmaceutical composition according to claim 1, wherein said at least three solvent-exposed amino acids appear on the molecular surface of the allergenic protein within a surface patch of approximately 500 square Angström.

3. (once amended) A pharmaceutical composition according to claim 1 [or 2 containing a peptide and a pharmaceutically acceptable carrier or diluent], wherein
[a) the peptide has a length of 8 to 50 amino acids;
b)] at least five consecutive amino acids of the peptide are identical to at least five consecutive solvent-exposed amino acids of the [amino acid sequence of an] allergenic protein[; and
c) said at least five consecutive amino acids are solvent-exposed amino acids in the allergenic protein].

4. (once amended) A pharmaceutical composition according to [any of claims 1 to 3] claim 1, further containing an adjuvant.

5. (once amended) A pharmaceutical composition according to [any of claims 1 to 4 characterized in that] claim 1, wherein all amino acids of the peptide except

one are identical to the amino acids of an amino acid sequence which is part of the allergenic protein amino acid sequence.

6. (once amended) A pharmaceutical composition according to claim 5, wherein [characterized in that] the one amino acid which deviates from the amino acid sequence of the allergenic protein is the N-terminal or C-terminal amino acid of the peptide amino acid sequence.

7. (once amended) A pharmaceutical composition according to [any of claims 1 to 4 characterized in that] claim 1, wherein the amino acid sequence of the peptide is identical to an amino acid sequence which is part of the allergenic protein amino acid sequence.

8. (once amended) A pharmaceutical composition according to [any of claims 1 to 7 characterized in that] claim 1, wherein the allergenic protein is the birch pollen allergen Bet v 1.

9. (once amended) A pharmaceutical composition according to [any of claims 1 to 8 characterized in that] claim 1, wherein the peptide amino acid sequence comprises at least the N-terminal or C-terminal five amino acids of the allergenic protein amino acid sequence.

14. (once amended) A method for [the preparation of] preparing a pharmaceutical composition comprising [the following steps]:

a) determining which amino acids of a given allergenic protein are solvent-exposed on the surface of the allergenic protein;

b) preparing a peptide having a length of 8 to 50 amino acids, wherein at least three preferably consecutive amino acids of the peptide are identical to at least three solvent-exposed amino acids of the allergenic protein which appear in close vicinity on the molecular surface of [an] the allergenic protein [wherein the at

least three amino acids are solvent-exposed amino acids in the allergenic protein]; and

c) optionally admixing the peptide with a pharmaceutically acceptable carrier or diluent.

15. (once amended) A method according to claim 14, wherein said at least three solvent-exposed amino acids appear on the molecular surface of the allergenic protein within a surface patch of approximately 500 square Angström.

16. (once amended) A method according to claim 14 [or 15 for the preparation of a pharmaceutical composition comprising the following steps:

a) determining which amino acids of a given allergenic protein are solvent-exposed on the surface of the allergenic protein;

b) preparing a peptide having a length of 8 to 50 amino acids], wherein at least five consecutive amino acids of the peptide are identical to at least five consecutive solvent-exposed amino acids of the [amino acid sequence of the] allergenic protein [wherein the at least five consecutive amino acids are solvent-exposed amino acids in the allergenic protein; and

c) optionally admixing the peptide with a pharmaceutically acceptable carrier or diluent].

17. (once amended) A method according to [any of claims 14 to 16] claim 14, further comprising [the addition of] adding an adjuvant.

18. (once amended) A method according to [any of claims 14 to 17 characterized in that] claim 14, wherein all amino acids of the peptide except one are identical to the amino acids of an amino acid sequence which is part of the allergenic protein amino acid sequence.

19. (once amended) A method according to claim 18, wherein [characterized in that] the one amino acid which deviates from the amino acid sequence of the allergenic protein is the N-terminal or C-terminal amino acid of the peptide amino acid sequence.

20. (once amended) A method according to [any of claims 14 to 17 characterized in that] claim 14, wherein the amino acid sequence of the peptide is identical to an amino acid sequence which is part of the allergenic protein amino acid sequence.

21. (once amended) A method according to [any of claims 14 to 20 characterized in that] claim 14, wherein the allergenic protein is the birch pollen allergen Bet v 1.

22. (once amended) A method according to [any of claims 14 to 21 characterized in that] claim 14, wherein the peptide comprises at least the N-terminal or C-terminal five amino acids of the allergenic protein amino acid sequence.

23. (once amended) A method according to [any of claims 14 to 22 characterized in that] claim 14, wherein the solvent-exposed amino acids of the allergenic protein are determined by determining the hydrophilicity profile of the [amino acid sequence of the] allergenic protein.

24. (once amended) A method according to [any of claims 14 to 22 characterized in that] claim 14, wherein the solvent-exposed amino acids of the allergenic protein are determined from the three-dimensional structure of the allergenic protein.